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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,519	02/24/2004	Michael D. O'Hara	CRD-5064	8314

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EXAMINER	
KOTINI, PAVITRA	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,519	O'HARA, MICHAEL D.	
	Examiner	Art Unit	
	Pavitra Kotini	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7, are rejected under 35 U.S.C. 102(b) as being anticipated by Froix (US-6248129).

Froix discloses:

Regarding claim 1, a structure for insertion into a living organism (11); and at least one radioprotective compound (glutathione; fig.12) affixed to the structure, the at least one radioprotective compound eluting from the structure and entering the surrounding tissue (col.15, lines 60-67) to protect the tissue from ionizing radiation.

Regarding claim 7, a stent (11); a polymeric matrix (col.13, lines 4-18) affixed to the surface of the stent; and at least one radioprotective compound (glutathione; example 21) incorporated into the polymeric matrix (col.15, line 60), the at least one radioprotective compound eluting from the polymeric matrix over a given time period

(fig. 12) and entering the surrounding tissue to protect the tissue from ionizing radiation (col.15, lines 38-40).

Claims 1-7 and 12-14 rejected under 35 U.S.C. 102(e) as being anticipated by Berstein et al. (US-2003/0220297).

Berstein discloses a medical device comprising:

Regarding **claim 1**, a structure for insertion into a living organism (stent); and at least one radioprotective compound (amifostine; para. 0122, 0221) affixed to the structure, the at least one radioprotective compound eluting from the structure and entering the surrounding tissue (para. 0135, 0142) to protect the tissue from ionizing radiation (aminfostine is a radioprotective compound so it inherently has the property of protecting tissue from ionizing radition).

Regarding **claim 2**, wherein the structure comprises a stent (para. 0141-0142).

Regarding **claim 3**, wherein the structure comprises a stent-graft (it is old and well known in the art that a stent-graft is a comparable and suitable devices for delivery of therapeutic compounds). See for example patent # 6503556.

Regarding **claims 4 and 12**, wherein the at least one radioprotective compound includes compounds comprising sulphur (para.0154).

Regarding **claims 5, 6, 13 and 14**, wherein the at least one radioprotective compound comprises an aminothiol such as amiphostine (para.0122).

Regarding **claim 7**, a stent (para.0123); a polymeric matrix (para.0123) affixed to the surface of the stent; and at least one radioprotective compound (para.0122) incorporated into the polymeric matrix, the at least one radioprotective compound

eluting from the polymeric matrix over a given time period and entering the surrounding tissue to protect the tissue from ionizing radiation (para.0142-0143).

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berstein et al. (US-2003/0220297) in view of Miller et al. (US-2003/0153983).

Berstein discloses the invention substantially as claimed above, but fails to teach polymeric matrix comprising a fluoropolymer and an acrylic.

However, Miller teaches a polymeric matrix comprises first and second polymers, wherein the first polymer comprises a fluoropolymer, and the second polymer comprises an acrylic (para.0038, 0058).

Therefore, it is old and well dknow in the art and would have been obvious to a person of ordinary skill in the art to modify the stent with the matrix as disclosed by Berstein to include the fluoropolymer and acrylic as part of the matrix. Such a composition would create a non-biodegradable, biocompatible matrix.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU 3731

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/7/07